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Attorneys for Defendant
MERCK & CO., INC. and Defendants and
Counterclaimants MERCK SHARP &
DOHME CORP. and ISIS
PHARMACEUTICALS, INC.

UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

GILEAD SCIENCES, INC.,

Plaintiff and
Counterdefendant,

v.

MERCK & CO., INC. (Defendant only), MERCK SHARP & DOHME CORP. and ISIS PHARMACEUTICALS, INC.

Defendants and
Counterclaimants.

Case No. 3:13-cv-04057-JSW

DEFENDANTS' ANSWER AND MERCK SHARP & DOHME CORP. AND ISIS PHARMACEUTICALS, INC.'S COUNTERCLAIMS

Ctrm: 11, 19th Floor
Judge: Honorable Jeffrey S. White

Defendants Merck & Co, Inc. ("Merck & Co."), Merck Sharp & Dohme Corp. ("MSD Corp.") and Isis Pharmaceuticals, Inc. ("Isis") (collectively, "Defendants"), for their answer to the Complaint of the Plaintiff, Gilead Sciences, Inc. ("Gilead"):

1. Admit that Gilead has asserted certain claims for declaratory judgment in this action, refer to Gilead's Complaint for the content thereof, and except as so admitted deny the allegations of paragraph 1.

2. Admit the allegations of paragraph 2 on information and belief.

3. Admit the allegations of paragraph 3.

4. Admit the allegations of paragraph 4.

5. Admit the allegations of paragraph 5.

6. Admit the allegations of paragraph 6.

7. Admit the allegations of paragraph 7.

8. Admit that the Court has personal jurisdiction over Merck & Co. and MSD Corp. for purposes of this action, and except as so admitted deny the allegations of paragraph 8.

9. Admit that a division of MSD Corp. has a place of business at 901 South California Avenue, Palo Alto, CA, 94304, and except as so admitted deny the allegations of paragraph 9.

10. Admit that MSD Corp. has derived substantial revenue from sales of pharmaceutical products in California, and except as so admitted deny knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 10.

11. Admit that the Court has personal jurisdiction over Isis, and except as so admitted deny the allegations of paragraph 11.

12. Admit that venue is properly laid in this judicial district, and except as so admitted deny the allegations of paragraph 12.

13. Admit that the Court has personal jurisdiction over Defendants for purposes of this action, and except as so admitted deny the allegations of paragraph 13.

14. Deny knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 14.

15. Admit that the Executive Director of Corporate Licensing at MSD Corp. made two unsolicited telephone calls to a Gilead employee and sent a letter addressed to Gilead in Foster City, CA, refer to the letter for the contents thereof, and except as so admitted deny the allegations of paragraph 15.

16. Admit the allegations of paragraph 16.

17. Admit the allegations of paragraph 17.

18. Admit the allegations of paragraph 18.

19. Admit that MSD Corp. and Isis are co-owners of the '499 patent, and except as so admitted deny the allegations of paragraph 19.

20. Admit the allegations of paragraph 20.

21. Admit the allegations of paragraph 21.

22. Admit that MSD Corp. and Isis are co-owners of the '712 patent, and except as so admitted deny the allegations of paragraph 22.

23. Deny knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 23.

24. Admit that Hepatitis C virus ("HCV") is classified into at least six distinct HCV genotypes (including genotypes 1-6) and that HCV may be spread by contact with HCV-infected blood and may infect the liver, and except as so admitted deny knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 24.

25. Deny knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 25.

26. Admit that chronic HCV infection has been treated with a combination of antiviral medications, including ribavirin, interferons and protease inhibitors, admit that these treatments may have limitations as to efficacy, may cause side effects, and may be prescribed for as long as 24 to 48 weeks, admit that liver transplantation can be life-saving for HCV-infected individuals with terminal end-stage liver disease, admit that transplantation presents significant risks, that there are donor shortages and that organ rejection may occur, admit that transplantation is costly and requires ongoing post-procedure care, and except as so admitted deny knowledge or information sufficient to form a belief

about the truth of the allegations of paragraph 26.

27. Admit that Gilead or its affiliates have developed an orally administered drug for treatment of chronic HCV infection called sofosbuvir, admit that sofosbuvir is a nucleotide analogue NS5B polymerase inhibitor for treatment of chronic HCV infection, admit that sofosbuvir may suppress replication of HCV RNA thereby interfering with HCV replication, deny that sofosbuvir was invented by Pharmasset, Inc. ("Pharmasset"), and except as so admitted or denied, deny knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 27.

28. Admit that sofosbuvir may be used for oral treatment of chronic HCV infection, and except as so admitted deny knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 28.

29. Admit that Gilead and Pharmasset issued a press release dated November 21, 2011, admit that Gilead issued a press release dated January 17, 2012, refer to the foregoing press releases for the terms thereof, and except as so admitted deny the allegations of paragraph 29.

30. Deny knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 30.

31. Admit that Gilead issued a press release dated June 7, 2013, refer to that press release for the terms thereof, and except as so admitted deny knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 31.

32. Deny knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 32.

33. Admit that MSD Corp. and its affiliates research, develop and market therapeutic pharmaceutical products, admit that some of those pharmaceutical products are for treatment of conditions that include infectious diseases, including HCV infection, and except as so admitted deny the allegations of paragraph 33.

34. Admit that MSD Corp. is the present holder of an FDA-approved New Drug Application ("NDA") for boceprevir, admit that boceprevir is marketed under the trade name VICTRELIS®, admit that annual sales of boceprevir currently exceed $500 million, and except as so admitted deny the

allegations of paragraph 34.

35. Admit that MSD Corp. or its affiliates gather certain information concerning competitor pharmaceutical companies, including Gilead, admit that such information includes information relating to drug development, clinical trials, corporate acquisitions and potential products for treatment of HCV infection, and except as so admitted deny the allegations of paragraph 35.

36. Admit the allegations of paragraph 36.

37. Admit the allegations of paragraph 37.

38. Admit that MSD Corp. or its affiliates monitor publicly available information concerning clinical trials of PSI-7977, and except as so admitted deny the allegations of paragraph 38.

39. Admit the allegations of paragraph 39.

40. Admit the allegations of paragraph 40.

41. Admit that MSD Corp. or its affiliates monitor publicly available information concerning FDA approval status of Gilead's NDA for sofosbuvir, and except as so admitted deny the allegations of paragraph 38.

42. Deny knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 42.

43. Admit that MSD Corp. has engaged in patent litigation, admit that MSD Corp. has commenced more than 25 patent infringement actions in the United States in the past 4 years, and except as so admitted deny the allegations of paragraph 43.

44. Admit that MSD Corp. has applied for and prosecuted patent applications relating to therapeutic products, admit that such activities include filing patent applications for compounds useful for treating HCV infection and methods of treating HCV infection, and except as so admitted deny the allegations of paragraph 44.

45. Admit that at some time during prosecution of U.S. Patent No. 7,105,499 ("the '499 patent"), MSD Corp. was aware that Pharmasset was seeking patent protection for compounds useful for treating HCV infection or methods of treating HCV infection, and except as so admitted deny the truth of the allegations of paragraph 45.

46. Admit that during prosecution of the '499 patent, MSD Corp. and Isis amended their pending claims, admit that the claims as amended encompass methods that were described in the application for the '499 patent and that are performed by administration to human subjects of certain compounds that were the subject of Pharmasset patent applications, and except as so admitted deny the allegations of paragraph 46.

47. Admit that at some time during prosecution of U.S. Patent No. 8,481,712 ("the '712 patent"), MSD Corp. was aware of Pharmasset compounds that may be useful for treatment of HCV infection, including a compound designated by Pharmasset as PSI-7977, and except as so admitted deny the allegations of paragraph 47.

48. Admit that during prosecution of the '712 patent, MSD Corp. and Isis amended their pending claims, admit that the claims as amended encompass compounds that were described in the application for the '712 patent and that result from use of PSI-7977, and except as so admitted deny the allegations of paragraph 48.

49. Admit that on July 29, 2013 Ms. Pamela Demain, Executive Director of Corporate Licensing at MSD Corp., made an unsolicited telephone call to the office number of Ms. Liz Bhatt, Gilead's Senior Director of Corporate Development, failed to reach Ms. Bhatt and left a message asking for a return call, admit that Ms. Bhatt called Ms. Demain called back on or about July 29 or 30, 2013, at which time Ms. Demain was not able to talk then, and except as so admitted deny the allegations of paragraph 48.

50. Admit that on August 2, 2013, Ms. Demain placed a further telephone call to Ms. Bhatt, failed to reach Ms. Bhatt and left a message asking for a return call, and except as so admitted deny the allegations of paragraph 50.

51. Admit that on August 5, 2013, Ms. Demain placed a further telephone call to Ms. Bhatt, admit that during that call Ms. Demain indicated that MSD Corp. was willing to grant Gilead a license under the '499 and '712 patents in relation to sofosbuvir, admit that Ms. Demain informed Ms. Bhatt of some terms of the offered license, and except as so admitted deny the allegations of paragraph 50.

52. Admit that on August 5, 2013, Ms. Demain sent Ms. Bhatt a letter by email, admit that a

copy of that letter is attached to Gilead's Complaint as Exhibit C, refer to the letter for the content thereof, and except as so admitted deny the allegations of paragraph 52.

53. Admit that Merck sent Gilead a letter dated August 5, 2013, refer to the aforesaid letter for the content thereof, and except as so admitted deny the allegations of paragraph 53.

54. Admit that Merck sent Gilead a letter dated August 5, 2013, refer to the aforesaid letter for the content thereof, and except as so admitted deny the allegations of paragraph 54.

55. Deny the allegations of paragraph 55.

56. Deny the allegations of paragraph 56.

57. Admit that Defendants believe that commercialization of sofosbuvir following FDA approval will directly or indirectly infringe the '499 and '712 patents, and except as so admitted deny the allegations of paragraph 57.

58. Deny the allegations of paragraph 58.

59. Admit that there is a substantial controversy between Gilead and Defendants regarding their respective rights and obligations under the '499 and '712 patents with respect to sofosbuvir and that this controversy is of sufficient immediacy and reality to warrant the exercise of declaratory judgment jurisdiction, and except as so admitted deny the allegations of paragraph 59.

60. Deny the allegations of paragraph 60.

61. Admit that the aforesaid controversy between Gilead and Defendants warrants the exercise of declaratory judgment jurisdiction, and except as so admitted deny the allegations of paragraph 61.

62. In response to paragraph 62, restate and reallege each of the forgoing paragraphs as if fully set forth herein.

63. Admit that an actual and justiciable case or controversy exists between Gilead and Defendants regarding their rights and obligations under the '499 patent with respect to sofosbuvir, and except as so admitted deny the allegations of paragraph 63.

64. Deny the allegations of paragraph 64.

65. Deny the allegations of paragraph 65.

66. In response to paragraph 66, restate and reallege each of the forgoing paragraphs as if fully set forth herein.

67. Admit that an actual and justiciable case or controversy exists between Gilead and Defendants regarding their rights and obligations under the '499 patent with respect to sofosbuvir, and except as so admitted deny the allegations of paragraph 67.

68. Deny the allegations of paragraph 68.

69. Deny the allegations of paragraph 69.

70. In response to paragraph 70, restate and reallege each of the forgoing paragraphs as if fully set forth herein.

71. Admit that an actual and justiciable case or controversy exists between Gilead and Defendants regarding their rights and obligations under the '712 patent with respect to sofosbuvir, and except as so admitted deny the allegations of paragraph 71.

72. Deny the allegations of paragraph 72.

73. Deny the allegations of paragraph 73.

74. In response to paragraph 74, restate and reallege each of the forgoing paragraphs as if fully set forth herein.

75. Admit that an actual and justiciable case or controversy exists between Gilead and Defendants regarding their rights and obligations under the '712 patent with respect to sofosbuvir, and except as so admitted deny the allegations of paragraph 75.

76. Deny the allegations of paragraph 76.

77. Deny the allegations of paragraph 77.

COUNTERCLAIMS

For its counterclaims against Gilead, Defendants MSD Corp. and Isis (collectively, "Counterclaimants") allege as follows:

PARTIES AND JURISDICTION

1. MSD Corp. is a corporation organized and existing under the laws of New Jersey, having

its principal place of business at One Merck Drive, P.O. Box 100, Whitehouse Station, NJ 08889-0100.

2. Isis is a corporation organized and existing under the laws of State of Delaware, having its principal of business at 2855 Gazelle Court, Carlsbad, CA 92010.

3. On information and belief, Gilead is a corporation organized and existing under the laws of State of Delaware, having its principal of business at 333 Lakeside Drive, Foster City, California 94404.

4. This action arises under the Patent Act of 1952, as amended, 35 U.S.C. §§ 1-376.

5. This Court has jurisdiction to hear this action under 28 U.S.C. §§ 1331 and 1338(a).

THE PATENTS-IN-SUIT

6. MSD Corp. and Isis are the owners of the '499 patent, entitled "Nucleoside Derivatives as Inhibitors of RNA-Dependent RNA Viral Polymerase," which the United States Patent and Trademark Office duly and legally issued on September 12, 2006 to MSD Corp.'s predecessor in interest and Isis.

7. MSD Corp. and Isis are the owners of the '712 patent, entitled "Nucleoside Derivatives as Inhibitors of RNA-Dependent RNA Viral Polymerase," which the United States Patent and Trademark Office duly and legally issued on July 9, 2013 to MSD Corp. and Isis.

8. By its Complaint, Gilead asserts claims against Counterclaimants for judgment declaring that commercial sale and use of sofosbuvir will not infringe any valid claim of the '499 and '712 patents and declaring that the claims of the '499 and '712 patents are invalid.

9. Counterclaimants deny Gilead's noninfringement and invalidity contentions, and contend that Gilead threatens to infringe the '499 and '712 patents by selling sofosbuvir following FDA approval.

10. An actual controversy has arisen and now exists between Counterclaimants and Gilead regarding the infringement and validity of the '499 and the '712 patents.

FIRST CLAIM FOR RELIEF

Declaratory Judgment of Infringement of the '499 Patent

11. Each of the proceeding paragraphs 1 to 10 is incorporated herein as if set forth in full.

12. On information and belief, Gilead has applied to the FDA for authorization to commercialize a chemical compound known as sofosbuvir for treatment of HCV infections in human

patients.

13. Sofosbuvir has been designated by Pharmasset as PSI-7977.

14. Sofosbuvir is a prodrug that, following administration to human subjects, is converted into a series of metabolites, including compounds designated as PSI-7411, PSI-7410 and PSI-7409.

15. The therapeutic benefit of sofosbuvir depends on its metabolism to PSI-7411, PSI-7410 and PSI-7409 following administration to human subjects.

16. The claims of the ’499 patent encompass methods of treating HCV infection by administering sofosbuvir to a human patient.

17. Upon commercialization of sofosbuvir, end users of sofosbuvir who administer the drug to HCV-infected human patients in the United States following FDA approval and prior to expiration of the ‘499 patent or any additional patent exclusivity accorded thereto will directly infringe the ‘499 patent.

18. When it filed its Complaint in this action Gilead had knowledge of the ‘499 patent.

19. On information and belief, when it filed its Complaint in this action Gilead had knowledge that sofosbuvir, upon administration to human subjects, is converted into metabolites, including PSI-7411, PSI-7410 and PSI-7409, and that the therapeutic benefit of sofosbuvir depends on such conversion.

20. On information and belief, when it filed its Complaint in this action Gilead had knowledge that end users of sofosbuvir who administer the drug to HCV-infected human patients in the United States, following FDA approval and prior to expiration of the ‘499 patent or any additional patent exclusivity accorded thereto, will directly infringe the ‘499 patent.

21. On information and belief, Gilead will actively induce infringement of the ‘499 patent by selling and offering for sale sofosbuvir in the United States, following FDA approval and prior to expiration of the ‘499 patent or any additional patent exclusivity accorded thereto, with a label that instructs end users to administer sofosbuvir to human patients for treatment of HCV infection.

22. Sofosbuvir has no substantial use that does not result in direct infringement of the ‘499 patent by end users in the United States.

23. On information and belief, Gilead will contribute to infringement of the ‘499 patent by selling and offering for sale sofosbuvir in the United States following FDA approval and prior to

expiration of the '499 patent or any additional patent exclusivity accorded thereto.

24. Gilead will have knowledge of any ruling by this Court that end users who use sofosbuvir in the United States in accordance with the directions in the product label will directly infringe the '499 patent. Gilead's commercialization of sofosbuvir in the United States following such a ruling and prior to expiration of the '499 patent or any additional patent exclusivity accorded thereto will induce and contribute to infringement of the '499 patent.

25. An actual controversy exists between Gilead and Counterclaimants concerning whether Gilead's threatened commercial sale and offer for sale of sofosbuvir in the United States will induce or contribute to infringement of the '499 patent.

SECOND CLAIM FOR RELIEF

Declaratory Judgment of Infringement of the '712 Patent

26. Each of the proceeding paragraphs 1 to 25 is incorporated herein as if set forth in full.

27. The claims of the '712 patent encompass PSI-7411, PSI-7410 and PSI-7409 that is produced by metabolism upon administering sofosbuvir to a human patient.

28. Upon commercialization of sofosbuvir, human patients to whom sofosbuvir is administered in the United States following FDA approval and prior to expiration of the '712 patent or any additional patent exclusivity accorded thereto will directly infringe the '712 patent.

29. When it filed its Complaint in this action Gilead had knowledge of the '712 patent.

30. On information and belief, upon FDA approval, Gilead will actively induce infringement of the '712 patent by selling and offering for sale sofosbuvir in the United States, following FDA approval and prior to expiration of the '712 patent or any additional patent exclusivity accorded thereto, with a label that instructs end users to administer sofosbuvir to human patients for treatment of HCV infection.

31. Sofosbuvir has no substantial use that does not result in direct infringement of the '712 patent by end users in the United States.

32. On information and belief, Gilead will contribute to infringement of the '712 patent by selling and offering for sale sofosbuvir in the United States, following FDA approval and prior to

expiration of the '712 patent or any additional patent exclusivity accorded thereto, with a label that instructs end users to administer sofosbuvir to human patients for treatment of HCV infection.

33. Gilead will have knowledge of any ruling by this Court that human patients to whom sofosbuvir is administered in the United States in accordance with the directions in the product label will directly infringe the '712 patent. Gilead's commercialization of sofosbuvir in the United States following such a ruling and prior to expiration of the '712 patent or any additional patent exclusivity accorded thereto will induce and contribute to infringement of the '712 patent.

34. An actual controversy exists between Gilead and Counterclaimants concerning whether Gilead's threatened commercial sale and offer for sale of sofosbuvir in the United States will induce or contribute to infringement of the '712 patent.

PRAYER FOR RELIEF

WHEREFORE Counterclaimants pray that the Court:

(i) declare, adjudge, and decree that Gilead's commercial sale and offer for sale of sofosbuvir will induce and contribute to infringement of the '499 patent;

(ii) declare, adjudge, and decree that Gilead's commercial sale and offer for sale of sofosbuvir will induce and contribute to infringement of the '712 patent;

(iii) issue an Order dismissing Gilead's Complaint with prejudice and entering judgment in favor of Defendants and Counterclaim Plaintiffs;

(iv) declare, adjudge, and decree that this case is exceptional and award Defendants and Counterclaim Plaintiffs their reasonable attorney's fees and costs pursuant to 35 U.S.C. §285;

(v) award such and further relief as the Court may deem just and proper.

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Dated: November 11, 2013

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By: */s/ Joshua H. Lerner*
JOSHUA H. LERNER

Attorneys for Defendant MERCK & CO., INC., and Defendants and Counterclaimants MERCK SHARP & DOHME CORP. and ISIS PHARMACEUTICALS, INC.

CERTIFICATE OF SERVICE

I certify that all counsel of record is being served on November 11, 2013 with a copy of this document via the Court's CM/ECF system.

/s/ Joshua H. Lerner
JOSHUA H. LERNER